

## **REMARKS**

### **Summary of the Office Action**

In the Office Action, Examiner:

- 1) Rejected Claim 5 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,480,410 ("Cuschieri et al.");
- 2) Rejected Claims 1-4, 8, 9, 12, 13, 15-19, and 21 under 35 U.S.C. § 103(a) as being unpatentable over Cuschieri et al. in view of U.S. Patent No. 4,802,474 ("Beevers");
- 3) Rejected Claims 6, 7, 10, and 11 under 35 U.S.C. § 103(a) as being unpatentable over Cuschieri et al. in view of Beevers and in further view of U.S. Patent No. 4,175,563 ("Arenberg et al.");
- 4) Rejected Claims 14 and 20 under 35 U.S.C. § 103(a) as being unpatentable over Cuschieri et al. in view of Beevers and in further view of U.S. Patent No. 3,618,606 ("Brown et al."); and
- 5) Rejected Claim 22 under 35 U.S.C. § 103(a) as being unpatentable over Cuschieri et al. in view of Beevers and in further view of U.S. Patent No. 5,976,118 ("Steer").

By this Reply, Claim 5 is cancelled, and Claims 1, 4, 20 and 22 are amended. Upon entry of the amendments, Claims 1-4 and 6-22 are pending.

### **Claim Amendments**

In order to overcome the claim rejections raised by Examiner and for clarification of the claimed features, an amended set of claims is submitted herewith.

Claim 1 has been amended and is now directed to a lesion or fistula isolating bag having two **internal** chambers which are separated by a flexible partition including a valve. More particularly, claim 1 is now directed to a lesion or fistula isolating bag comprising a bag having a closable entrance, a closure for the closable entrance, and attachment means for affixing the bag to the skin of a patient over a wound. The bag contains two chambers, one of which includes the closable entrance, and the other of which provides access to the wound. A flexible partition separates the two chambers and includes a valve having a twofold function of inhibiting passage of fluid from the wound through the second chamber to the first chamber and allowing access to the wound through the second chamber.

These features are neither disclosed nor suggested in the two references cited by Examiner against claim 1, namely Cuschieri et al. and Beevers.

Cuschieri et al. discloses an extra-corporeal pneumo-peritoneum access bubble comprising an enclosure 2 having an access opening 5 in the form of an iris valve 11. The iris valve 11 as shown in FIG. 3 comprises a tube 13 attached at its opposite ends to a pair of rings 12, which twist in opposite directions to form the valve. Examiner has described this iris valve as first and second chambers accessible one from the other through the central opening of the valve 11. Examiner stated that the entrance of one such chamber is fully capable of being closed.

However, this is not what Cuschieri et al. teaches. Cuschieri et al. teaches an enclosure 2 providing a single chamber, and an iris valve 11 in the surface of the enclosure 2. The iris valve 11 constitutes the whole of the tube 13, rings 12, and central opening – at no stage does Cuschieri et al. describe this valve arrangement as two separate chambers in itself.

Accordingly, with reference to amended claim 1, Cuschieri et al. contains a teaching of a closure 11 for a closable entrance 5, but no teaching of same based on Examiner's view of the closable entrance being one end of the tube 13. Even if Cuschieri et al. is taken to teach the enclosure 2 defining one chamber, then the iris valve 12 forms a partition between the enclosure 2 and the outside, but there is no second chamber. Certainly, Cuschieri et al. contains no teaching of first and second chambers within a bag, nor a flexible partition separating first and second chambers and including a valve for inhibiting the passage of fluid between the chambers on the one hand and allowing access to the wound of a patient through the chambers on the other hand.

The provision of two different chambers according to the present invention provides a much more effective seal both for preventing seepage of fluid from the wound to the exterior and for isolating the wound from the surrounding atmosphere. This ensures added security against leakage of wound discharge and infection of the wound.

Examiner argued that Beevers discloses the features not present in Cuschieri et al., but again it is submitted that this is not the case. Beevers discloses a protective cover for a tracheotomy tube according to which a vent flange 12 or 17 is attached to a tracheal tube 15 and conceals an incision in the skin through which the tracheal tube 15 is inserted. This device bears

no resemblance to the access bubble of Cuschieri et al., and a person of ordinary skill in the art would certainly not affix the tracheal tube 15 as a closure in the opening 12, which is designated by Examiner to be the closable opening of one chamber. The result would be neither a functioning tracheotomy tube nor a functioning extra-corporeal pneumo-peritoneum access bubble.

Claim 20 has been amended for consistency with claim 1. Examiner has further cited Brown et al. against claim 20. However, Brown et al. discloses a stoma bag formed of flat sheets of material, in which a single enclosure formed from sheets 20, 21 has a closable access opening 34 in one wall 21 and a mounting pad 30 affixed to the outer wall 20 for securing the bag to the patient's skin. The mounting pad 30 contains an access orifice 29.

Accordingly, Brown et al. does not disclose or teach both a vessel and a bag, as in claim 20, in which the vessel and the bag are joined together, thereby assuring that the joining comprises first and second adjacent layers of material, such that a slit in one of the bag or the vessel is offset from a slit in the other of the bag or the vessel. Further, even if Examiner combined Cuschieri et al., Beevers, and Brown et al., the result would not be the present invention according to claim 20 because adjacent layers of material with offset slits are not disclosed in any of these three references.

Claim 22 has been amended to correct a typographical error.

**CONCLUSION**

In view of the foregoing Amendments and Remarks, Applicant respectfully requests the Examiner to reconsider the rejections and allow Applicant's claims as amended. If deficiencies remain, the Examiner may contact the undersigned to facilitate allowance of this case.

Respectfully submitted,

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By: /Peter M. Klobuchar/  
Peter M. Klobuchar, Reg. No. 43,722  
Ungaretti & Harris LLP  
70 West Madison Street, Suite 3500  
Chicago, Illinois 60602  
312.977.4400